Appendix 8 - 510(k) Summary

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Paula A. Torrianni, Associate Director, Regulatory Affairs
Date Prepared:	November 8, 2004
Trade name:	*Vigilance II* Continuous Cardiac Output/Oximetry/Volumetric (CCO/SvO_2/CEDV) Monitor
Classification Name:	Cardiac Output/Oximeter/Ejection Fraction Computer Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435)
Predicate Devices:	*Vigilance* Continuous Cardiac Output/Oximetry/Continuous End Diastolic Volume (CCO/SvO_2/CEDV) Monitor
Device Description:	The *Vigilance II* CCO/SvO_2/CEDV Monitor is a microprocessor-based instrument which, when connected to an appropriate Edwards catheter, measures cardiac output both continuously (CCO) and by the intermittent bolus (injectate) method (ICO), as well as continuously generates right ventricular ejection fraction (RVEF) and end diastolic volume (EDV). When connected to an Edwards oximetry catheter, the monitor measures oxygen saturation (oximetry).
Intended Use:	The *Vigilance II* CCO/SvO_2/CEDV Monitor is intended to measure ICO, CCO, oximetry and RVEF and EDV, and calculate derived hemodynamic and oxygenation parameters.
Comparative Analysis:	The *Vigilance II* CCO/SvO_2/CEDV Monitor has been demonstrated to be as safe and effective as the predicate device for its intended use.
Functional/Safety Testing:	The *Vigilance II* CCO/SvO_2/CEDV Monitor has successfully undergone functional testing as well as electrical safety testing, demonstrating equivalence to the predicate device.
Conclusion:	The *Vigilance II* CCO/SvO_2/CEDV Monitor is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 9 2004

Edwards Lifesciences LLC
c/o Ms. Paula A. Torrianni
Associate Director, Regulatory Affairs
One Edwards Way
Irvine, CA 92614

Re: K043103
Trade Name: Vigilance II CCO/SvO_2/CEDV Monitor
Regulation Number: 21 CFR 870.1425
Regulation Name: Programmable Diagnostic Computer
Regulatory Class: II (two)
Product Code: DXG
Dated: November 08, 2004
Received: November 09, 2004

Dear Ms. Torrianni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Lochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix 2 - Indications for Use Statement

510(k) Number (if known): K043103

Device Name: *Vigilance II* CCO/SvO_2/CEDV Monitor

Indications for Use:

The *Vigilance II* CCO/SvO_2/CEDV Monitor is indicated for use in patients requiring monitoring of hemodynamic parameters, including cardiac output, oximetry and right ventricular ejection fraction and end diastolic volume measurements.

Prescription Use ___X___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachuska

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043103